



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

**Proposed Project: Data System for Organ Procurement and Transplantation Network and Associated Forms (OMB No. 0915-0157) - Extension.**

Section 372 of the Public Health Service (PHS) Act requires that the Secretary, by contract, provide for the establishment and operation of an Organ Procurement and Transplantation Network (OPTN). The OPTN, among other responsibilities, operates and maintains a national waiting list of individuals requiring organ transplants, maintains a computerized system for matching donor organs with transplant candidates on the waiting list, and operates a 24-hour system to facilitate matching organs with individuals included in the list.

Data for the OPTN data system are collected from transplant hospitals, organ procurement organizations, and tissue-typing laboratories. The information is used to indicate the disease severity of transplant candidates, to monitor compliance of member organizations with OPTN rules and requirements, and to report periodically on the clinical and scientific status of organ donation and transplantation in this country. Data are used to develop transplant, donation and allocation policies, to determine if institutional members are complying with policy, to determine member specific performance, to ensure patient safety when no alternative sources of data exist and to fulfill the requirements of the OPTN Final Rule. The practical utility of the data collection is further enhanced by requirements that the OPTN data must be made available, consistent with applicable laws, for use by OPTN members, the Scientific Registry of Transplant Recipients, the Department of Health and Human Services, and others for evaluation, research, patient information, and other important purposes.

The OPTN is recommending addition of a new Liver Explant Pathology form to the OPTN data system. This new form was developed by the OPTN Liver and Intestinal Organ Transplantation Committee and will be used to collect pathology data on liver transplant recipients who received waitlist exception points as a result of a diagnosis of hepatocellular carcinoma. Existing OPTN policy requires submission of post-transplant pathology reports by fax transmission, and the proposed form will provide standardized collection of this already-required information.

There are also minor revisions to the existing data collection forms; the added fields were inadvertently left off of the forms at the time of the initial submission. Several of these fields are

“read only” and are included on the forms for information purposes only. One field is proposed to be removed as it represented duplicative information.

The annual estimate of burden is as follows:

Form	Number of respondents	Responses per respondents	Total responses	Hours per response	Total burden hours
Deceased Donor Registration	58	228	13,224	0.7500	9,918.00
Death referral data	58	12	696	10.0000	6,960.00
Death Notification Referral – Eligible	58	145	8410	0.5000	4,205.00
Death Notification Referral – Imminent	58	124	7192	0.5000	3,596.00
Living Donor Registration	311	23	7153	0.6500	4,649.45
Living Donor Follow-up	311	78	24,258	0.5000	12,129.00
Donor Histocompatibility	158	94	14,852	0.1000	1,485.20
Recipient Histocompatibility	158	171	27,018	0.2000	5,403.60
Heart Candidate Registration	131	27	3,537	0.5000	1,768.50
Lung Candidate Registration	66	41	2706	0.5000	1,353.00
Heart/Lung Candidate Registration	50	1	50	0.5000	25.00
Thoracic Registration	131	34	4454	0.7500	3,340.50
Thoracic Follow-up	131	277	36,287	0.6500	23,586.55
Kidney Candidate Registration	239	154	36,806	0.5000	18,403.00
Kidney Registration	239	72	17,208	0.7500	12,906.00
Kidney Follow-up *	239	693	165,627	0.5500	91,094.85
Liver Candidate Registration	132	98	12,936	0.5000	6,468.00
Liver Registration	132	48	6,336	0.6500	4,118.40
Liver Explant Pathology	132	11	1,452	0.3400	493.68
Liver Follow-up	132	459	60,588	0.5000	30,294.00
Kidney/Pancreas Candidate Registration	144	11	1,584	0.5000	792.00
Kidney/Pancreas Registration	144	6	864	0.9000	777.60
Kidney/Pancreas Follow-up	144	75	10,800	0.8500	9,180.00
Pancreas Candidate Registration	144	4	576	0.5000	288.00
Pancreas Islet Candidate Registration	23	5	115	0.5000	57.50
Pancreas Registration	144	2	288	0.7500	216.00
Pancreas Follow-up	144	23	3312	0.6500	2,152.80
Intestine Candidate Registration	43	5	215	0.5000	107.50
Intestine Registration	43	3	129	0.9000	116.10
Intestine Follow-up	43	25	1075	0.8500	913.75

Post Transplant Malignancy	689	11	7579	0.2000	1,515.80
Total *Includes an estimated 2,430 kidney transplant patients transplanted prior to the initiation of the data system.			478,270		258,314.78

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by email to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974. Please direct all correspondence to the “attention of the desk officer for HRSA.”

Dated: January 12, 2012

Reva Harris

Acting Director, Division of Policy and Information Coordination

[FR Doc. 2012-954 Filed 01/18/2012 at 8:45 am; Publication Date: 01/19/2012]